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| 09/764,163 | 01/16/2001 | Robert F. Balint | 021167-000710US | 7613 |
| 20350 7590 05/28/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | | |
| EXAMINER | | | | |
| GROSS, CHRISTOPHER M | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1639 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/764,163

Applicant(s)

BALINT ET AL.

Examiner

CHRISTOPHER M. GROSS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80, 85, 90-92, 98 and 99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80, 85, 90, 91, 92, 98, 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Responsive to communications entered 11/16/2007 and 3/7/2008. Claims 80,85,90,91,92,98,99 are pending. Claims 80,85,90,91,92,98,99 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/2007 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

This application filed 1/16/2001 claims benefit of 60/175,968 filed 01/13/2000 and is a CIP of 09/526,106 filed 03/15/2000 (now ABN). It is noted, however, support for: circularly permuted beta lactamases bearing two break-points and interactor domains

bearing thioredoxin peptide sequences does not find support in the earlier application(s). See also 35 USC 112 first considerations concerning "new matter" below.

Therefore 1/16/2001 is the date for the purposes of prior art concerning claims 80,85,90,91,92,98,99.

Withdrawn Objection(s) and Rejection(s)

The rejection of claims 87-88 and 93-97 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for circularly permuted beta-lactamase comprising N and C interactor domains with a breakpoint between Glu197 and Leu198 it, does not reasonably provide enablement for the other breakpoints set forth in claim 80 is hereby withdrawn in view of applicant's cancellation of the claims.

The rejection of claims 80, 84, 85 under 35 U.S.C. 102(b) as being anticipated by Pieper et al (1997 Biochemistry 36:8767 - IDS entry 5/5/2004) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 80,84-85,87-88,90-97 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

The objection to claim 87 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim in view of applicant's cancellation of the claim.

The rejection of claims 80,84-85,87-88,90-97 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is hereby withdrawn in view of applicant's amendments and/or cancellation of the claims.

Maintained Claim Rejection(s) - 35 USC § 112

Claims 80,85,90,91,92,98,99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for circularly permuted beta-lactamase comprising N and C interactor domains with a breakpoint between Glu197 and Leu198 it, does not reasonably provide enablement for the other breakpoints set forth in claim 80.

Response to Arguments

Applicant argues, see paragraph bridging pp 11-12 of remarks entered 11/16/2007, that the presently amended claim 80 recites a breakpoint within the solvent exposed loop between residues Thr 195 and Ala 202.

The examiner respectfully disagrees. Claim 80 has been amended between lines 18 and 21 to read "wherein said N-terminal break-point and said C-terminal break-point of the circularly permuted TEM-1 beta-lactamase protein are between 2 amino acid residues in a solvent exposed loop between amino acid residues Thr 195 and Ala 202..." Emphasis added. This phrase reads on a circularly permuted beta-lactamase

with *two* break points. The specification as filed does not provide enablement for circularly permuted beta-lactamase deletion mutants (i.e. missing residues from the newly formed N and C termini.)

In so far as claim 85 is concerned, which recites in the last two lines, which recite wherein "said C-terminal break-point **and** said N-terminal break-point is between amino acid residues Glu 197 and Leu 198," (emphasis added), it is similarly noted that this limitation reads on a Glu-Leu dipeptide deletion. The specification as filed does not provide enablement for circularly permuted beta-lactamase deletion mutants including missing Glu 197 and Leu 198.

See also 35 USC 112 first paragraph considerations concerning "new matter" below.

Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80,85,90,91,92,98,99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 80 has been between lines 18 and 21 to read “wherein said N-terminal break-point and said C-terminal break-point of the circularly permuted TEM-1 beta-lactamase protein are between 2 amino acid residues in a solvent exposed loop between amino acid residues Thr 195 and Ala 202...”

This limitation embraces circular permuted beta lactamases which delete various dipeptide, tripeptide, tetrapeptide, pentapeptide, hexapeptide or heptapeptide sequences between Thr 195 and Ala 202 of the parent beta lactamase.

Claim 80 has been amended to bear interactor domains including members of a thioredoxin peptide library. Said thioredoxin peptide library members read on small peptides derived from the primary sequence of thioredoxin.

The specification as originally filed provided no implicit or explicit support for circular permuted beta lactamase deletion mutants or interactor domains bearing small thioredoxin derived peptides.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes “If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a

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claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/Mark L. Shibuya, Ph.D./
Primary Examiner, Art Unit 1639